K010405

MAR 1 3 2001

510(k)
7230 Ultrasound Imaging System with TEI
Biosound Esaote

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
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Contact Person: Colleen Hittle

Date: February 5, 2001

807.92(a)(2)

Trade Name:	7230 Ultrasound Imaging System with TEI	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system	892.1550
Classification Number:	90IYN 90IYO	

807.92(a)(3)

Predicate Device(s)

Esaote	7230	K982444 + 994369

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k)
7230 Ultrasound Imaging System
Biosound Esaote

807.92(a)(5)

Intended Use(s)

Specific information about uses is provided in the operator's manual. Generally, the system is intended to be used by or under the direction of a physician for diagnostic imaging in cardiac, abdominal, peripheral vascular, fetal, neonatal head, small organs, pediatric, transrectal, and transvaginal applications.

510(k) Summary
7230 Ultrasound Imaging System
Biosound Esaote

Comparison Chart for Substantial Equivalence

General Characteristics	Esaote	Esaote
	7230	**7250 (Megas)**
Electrical Safety	IEC60601-1	IEC60601-1
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)
Intended Use		
• Cardiac (Transthoracic)	YES	YES
• Cardiac (Transesophageal)	NO	YES
• Vascular	YES	YES
• Abdominal	YES	YES
• Fetal	YES	YES
• Adult Transcranial	No	YES
• Neonatal Head/Small parts	YES	YES
• Endovaginal	YES (Sagittal & Transverse Planes)	YES (Sagittal & Transverse Planes)
• Endorectal	YES (Sagittal & Transverse Planes)	YES (Sagittal & Transverse Planes)
Probe Technology		
• Annular Array	No	YES
• Phased Array	YES	YES
• Linear array	YES	YES
• Convex Array	YES	YES
Modes of operation	Fundamental and Harmonic Imaging, PW, CW, CFM	Fundamental and Harmonic Imaging, PW, CW, CFM
Imaging Frequencies	2.0, 2.5, 3.5, 5.0, 7.5, 10 MHz	2.0, 2.5, 3.5, 5.0, 7.5, 10 MHz
CFM/Doppler Frequencies	2.0, 2.5, 3.3, 5.0 MHz	2.0, 2.5, 3.3, 5.0 MHz
Biopsy Guidance	YES	YES
• Biopsy Intended Uses	General Purpose and Transrectal /transvaginal	General Purpose and Transrectal /transvaginal
• Biopsy Line Depth marker	1 cm	1 cm
Display Type	SVGA	SVGA
Digital Archival Capabilities	YES	YES
VCR / Page Printer	YES	YES
M&A Capabilities	Cardiac, Vascular, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2001

Ms. Collen J. Hittle
Offical Correspondent
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K010405
Trade Name: 7230 Ultrasound Imaging System With TEI
Regulatory Class: II/21 CFR 892.1550/21 CFR 892.1560
Product Code: 90 IYN/90 IYO
Dated: February 7, 2001
Received: February 12, 2001

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 7230 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Numbers:

PA220
PA121
PA122
PA023
CA621
LA522
LA523
TRT12

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Mod.7230

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		[2]	N[3]
Abdominal		N	N	N		N	N		[2]	N[3]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		[2]	N[3]
Small Organ (specify) [1]		N	N	N	N	N	N		[2]	
Neonatal Cephalic		N	N	N	N	N	N		[2]	
Adult Cephalic										
Cardiac		N	N	N	N	N			[2]	N[3]
Transesophageal										
Transrectal		N	N	N		N	N		[2]	
Transvaginal		N	N	N		N	N		[2]	
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		[2]	
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Small organs include Thyroid, Breast and Testicles. [2] Applicable combined modes: B+M+PW+CW+CFM+PD. [3] Tissue Harmonic Imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010405

Prescription Use /

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA220**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P			[1]	P[2]
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Applicable combined modes: B+M+PW+CW+CFM+PD. [2] Tissue Harmonic Imaging

This probe has been previously cleared by FDA (K982444 and K994369).

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010465

Prescription Use ✓

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA121**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		[1]	N[2]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		[1]	N[2]
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N			[1]	N[2]
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication: P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Applicable combined modes: B+M+PW+CW+CFM+PD. [2] Tissue Harmonic Imaging

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010405

Prescription Use ✓

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA122**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		[1]	
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		[1]	
Adult Cephalic										
Cardiac		N	N	N	N	N			[1]	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		[1]	
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Applicable combined modes: B+M+PW+CW+CFM+PD.

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010405

Prescription Use ✓

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA023**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		[1]	
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		[1]	
Adult Cephalic										
Cardiac		N	N	N	N	N	N		[1]	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		[1]	
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Applicable combined modes: B+M+PW+CW+CFM+PD.

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concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓

510(k) Number K012425

Diagnostic Ultrasound Indications for Use Form

Transducer: **CA621**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		[1]	N[2]
Abdominal		N	N	N	N	N	N		[1]	N[2]
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Applicable combined modes: B+M+PW+CW+CFM+PD. [2] Tissue Harmonic Imaging

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010405

Diagnostic Ultrasound Indications for Use Form

Transducer: **LA522**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		N	N	N		N	N		[2]	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		[2]	
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Small organs include Thyroid, Breast and Testicles. [2] Applicable combined modes: B+M+PW+CW+CFM+PD.

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concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jayson

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010405

Prescription Use ✓

Diagnostic Ultrasound Indications for Use Form

Transducer: **LA523**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		N	N	N		N	N		[2]	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		[2]	
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments: [1] Small organs include Thyroid, Breast and Testicles. [2] Applicable combined modes: B+M+PW+CW+CFM+PD.

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Prescription Use ✓

David A. Syrowski

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010405

Diagnostic Ultrasound Indications for Use Form

Transducer: **TRT12**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		[1]	
Transvaginal		P	P	P		P	P		[1]	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

N=new indication: P=previously cleared by FDA; E= added under Appendix E

Additional Comments: This transducer has been previously cleared by FDA with the AU3 unit (K953716). [1]

Applicable combined modes: B+M+PW+CW+CFM+PD.

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010405

Prescription Use ✓